

# Office of Attorney General Terry Goddard



STATE OF ARIZONA  
DEPARTMENT OF LAW  
1275 W. WASHINGTON STREET  
PHOENIX, ARIZONA 85007-2926  
[WWW.AZAG.GOV](http://WWW.AZAG.GOV)

ANDREA M. ESQUER  
PRESS SECRETARY  
PHONE: (602) 542-8019  
CELL PHONE: (602) 725-2200

FOR IMMEDIATE RELEASE

---

## **Attorney General Settles with Heart Device Maker for \$16.75 Million**

(Phoenix, Ariz. – Aug. 30, 2007) Attorney General Terry Goddard today announced a \$16.75 million settlement with Guidant Corporation, a wholly owned subsidiary of Boston Scientific and one of the world's top three manufacturers of Implantable Cardioverter Defibrillators (ICDs). The settlement resolves allegations that the company sold a type of ICD with short-circuiting defects without notifying consumers or doctors of the defects.

Goddard joined Attorneys General of 35 other states and the District of Columbia in this settlement. Arizona will receive \$815,000 which will be used to fund consumer fraud education and investigations and enforcement of the Consumer Fraud Act. The settlement does not constitute an admission of wrongdoing by Guidant Corporation.

ICDs are medical devices that doctors surgically implant in a patient's chest to detect abnormal heart rhythms. If the heart stops, the ICD delivers a small jolt of electricity to start the heart functioning again. The settlement relates to the sale of the ICD known as the Ventak Prizm 2 DR Model 1861 (Prizm).

According to court documents, Guidant began making changes to Prizm devices in 2002 to correct a defect that could cause the unit to short circuit. If the Prizm short-circuited, it could fail to deliver a life-saving jump-start to a patient's heart.

Guidant continued to sell unmodified Przims even after making two separate changes to correct the defect. In 2005, the state Attorneys General began investigating Guidant after doctors contacted The New York Times. The company sold 4,000 unmodified devices in 2002-2003, but did not inform physicians or the public of the potential problems until May 2005.

Currently, Guidant is conducting a warranty program to provide consumers who wish to replace their Przims with a new device and reimburse them up to \$2,500 for out-of-pocket expenses associated with the replacement. Under today's settlement, Guidant has agreed to extend this warranty program for an additional six months. The States

will use up to \$1 million of the \$16.75 million settlement to reimburse warranty program participants for expenses they incurred beyond \$2,500.

Guidant also agreed to do the following:

- Establish a patient safety advisory board consisting of independent experts to evaluate data concerning ICD performance.
- Establish a patient safety officer position, staffed by a physician, whose primary responsibility is to advance ICD patient safety.
- Clearly disclose and disseminate to the public specific information on a quarterly basis, including worldwide failure data, survival probability estimates and current information in the event of an FDA recall of any ICD.
- Post a notice on its Web site within 30 days of any modification to any of its ICDs to correct a failure pattern.
- Solicit the return of out-of-service ICDs.
- Maintain a data system to track the serial numbers, implant dates and explant dates of all ICDs it distributes in the United States.

Consumers who may be affected by this settlement will be enrolled in the warranty program through their doctor. Assistant Attorney General Noreen Matts handled this case.

###